

Application No.: 10/797,946
Docket No.: 632898-042-C1
Response to Office Action mailed April 19, 2006
Page 6

RECEIVED
CENTRAL FAX CENTER
OCT 19 2006

REMARKS/ARGUMENTS

Claims 1-25 are pending in this application. Claims 1 and 12 have been amended. Review and reconsideration on the merits are requested in view of the foregoing amendments and the following discussion.

Claims 2, 4, 6, 8, 12, 13, 15, 17, 18, 21, 22 and 24 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office has raised a concern with the term "and/or" in claims 1 and 12. Applicants submit that the term is clear. It refers to situations wherein either one or both of the conditions is met. For example, in claim 12 the method can provide an amount of calcium, an amount of magnesium or an amount of calcium and magnesium. Applicants respectfully submit that this terminology is clear and request that the rejection be withdrawn with respect to the use of this term.

The Office also objects to the use of the word "safe." This term is common in pharmaceutical applications and is accepted in the field. Furthermore, applicants have defined the term in paragraph [0028] of the application. Therefore, applicants submit that the term is not indefinite and request that the rejection be withdrawn with respect to this term.

According to the Office action, the term "from about" is a relative term that renders the claims indefinite. Applicants respectfully submit that the claims as presented satisfy the requirements of §112 and are not indefinite. "[T]he term 'about' . . . is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217. (Fed. Cir. 1995)). The Office action indicates that the term is relative and, therefore, indefinite since it "is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Office action page 2-3. The Federal Circuit recently reversed a lower court making the same argument with respect to the term "substantially" finding that "the court erred in law, in requiring that the intrinsic evidence of the specification and prosecution history is the sole source of meaning of words that are used in a technologic context....[T]he patentee is not required to include in the specification information readily understood by practitioners." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002). Applicants respectfully submit that the term "from about"

Application. No.: 10/797,946
Docket No.: 632898-042-C1
Response to Office Action mailed April 19, 2006
Page 7

would be understood by persons in the relevant field and, therefore, satisfies the requirements of 35 U.S.C. §112. One of ordinary skill in the field of the invention would understand that the term "from about" is simply used to "avoid a strict numerical boundary to the specified parameter." *Pall Corp.* at 1217. Therefore, for the reasons set forth above, applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

Claims 6 and 8 are also considered by the Office to be unclear because of the term "on an elemental calcium basis." Applicants again submit that the term is clear and furthermore is defined in the application at paragraph [0030]. Therefore, for the reasons set forth above, applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

Claims 1-11 stand rejected under 35 U.S.C. §112, first paragraph as being non-enabled for preventing conditions associated with calcium or magnesium deficiency. Applicants have amended claim 1 to refer to treating these conditions as opposed to preventing conditions. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Electronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) (*citing Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)). Applicants respectfully submit that the specification, when combined with information known in the art, satisfies the enablement requirement for claim 1 as amended. Therefore, applicants respectfully request that the rejection under §112 be withdrawn.

Claims 1, 3, 5-6, 9, 11, 12 and 14 stand rejected as being anticipated by U.S. Pat. No. 6,031,000 to Nissen et al. It is respectfully submitted that the Nissen document fails to disclose or suggest the present invention. Independent claims 1 and 12 of the present application recite treating a subject having a condition associated with calcium and/or magnesium deficiency and treating a subject in need of a nutritionally supplemental amount of calcium and/or magnesium and said mineral supplement is administered in an amount sufficient to supply said nutritionally supplemental amount, respectively. These limitations are not disclosed or described in Nissen. It is axiomatic that all limitations must be considered in determining anticipation. Since these limitations are not present in Nissen there can be no anticipation. To the extent the Office is taking the position that such disclosure is inherent, applicants respectfully disagree. Reliance on an inherent disclosure in a reference must be based on more than mere conjecture. "In relying

Application. No.: 10/797,946
Docket No.: 632898-042-C1
Response to Office Action mailed April 19, 2006
Page 8

upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original) Accordingly, it is respectfully submitted that the Nissen document fails to disclose or suggest the invention claimed in the present application. Accordingly, it is respectfully requested that the rejection of these claims be withdrawn.

Claims 1, 5-6 and 9 stand rejected as being anticipated by the Vukovich article. Vuckovich suffers from the same problem as Nissen in that it fails to disclose or suggest treating a subject having a condition associated with calcium and/or magnesium deficiency or treating a subject in need of a nutritionally supplemental amount of calcium and/or magnesium. Vuckovich never indicates or suggests that the composition is being administered to address one of these matters. Muscle loss is described as being due to "poor nutrition, lack of exercise or use, a reduction in motor units activated, and/or the loss of contractile or mechanical properties." Nowhere is calcium deficiency mentioned. Again any argument that the anticipation is inherent is mere conjecture and insufficient as a basis to reject the claims. Accordingly, it is respectfully requested that the rejection of these claims be withdrawn.

The same reasoning applies to the rejection claims 1, 5-6, 7-9, and 12 over WO 94/17678. The '678 document discloses orally administering HMB to pregnant mammals to increase the nutritional value of colostrum in breast milk of the treated mammals. The reference does not disclose or suggest treating calcium and/or magnesium deficiency by administering a mineral supplement containing calcium HMB, magnesium HMB or both to a subject in need thereof. Accordingly, it is respectfully requested that the rejection of these claims be withdrawn.

Claims 1-25 stand rejected as being unpatenable over Nissen et al. taken with Vukovich et al. and the '678 publication in view of www.naturalconnections.com (1998). The Office action indicates that it would have been obvious to combine these references to arrive at the present invention. However, applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness because there is no suggestion in the prior art to combine these references as suggested by the Office. Although a reference need not expressly teach that the disclosure contained therein should be combined with another or modified, the showing must

Application No.: 10/797,946
Docket No.: 632898-042-C1
Response to Office Action mailed April 19, 2006
Page 9

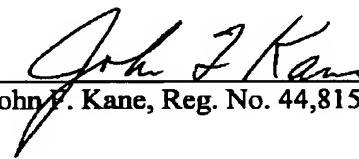
nevertheless be "clear and particular." *Winter Royalty Corp. v Wang*, 202f.3d 1340, 1348-1349 (Fed. Cir. 2002). Certainly, there is nothing recited in the cited references that provides "clear and particular" motivation to one of ordinary skill in the art to make the modifications as proposed in the Office action. Therefore, for at least this reason applicants submit that the claims are patentable over the cited references and request that the rejections be withdrawn.

Furthermore, with respect to claims 2, 13, 17, 18, and 19 – 25, which are directed to methods and compositions containing a combination of calcium and magnesium, the cited references fail to disclose or suggest such a combination. Although the Naturalconnections.com document describes the combination of magnesium and calcium, it fails to disclose a mineral supplement containing calcium HMB and magnesium HMB. Furthermore, there is no motivation in the art or any of the cited references for modifying these teachings to arrive at the present invention. Therefore, for at least this reason as well applicants submit that these claims are patentable over the cited references and request that the rejections be withdrawn.

The claims also stand rejected based on double patenting over U.S. application 10/658075. The '075 application has been abandoned thereby rendering this rejection moot.

In view of the foregoing, it is respectfully submitted that claims currently pending are distinguishable from the references cited and are in condition for allowance. Reconsideration of the rejections of record is respectfully requested. If the examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,


John J. Kane, Reg. No. 44,815

THOMPSON HINE LLP
2000 Courthouse Plaza, N.E.
10 West Second Street
Dayton, Ohio 45402-1758
937-443-6816